science, it's part of discovery. We rationalized it afterwards. What happened is the benzalkonium chloride had complexed with the saccharin sodium, which is the sweetening agent. That is a nice example of what I mentioned yesterday where we have eleven ingredients and add a twelfth to this cocktail and anything could happen. It did in this case. If we have an incompatibility between two ingredients, we would discount the one that was being suggested as a new introduction.

So the one other is listed here, phenol. Keeping a very broad perspective on this, we knew that phenol was used in the injection, the Zantac injection. That means it's compatible with ranitidine. Two questions: Does it kill the bug and can we take it by mouth? Plus some of the other questions I mentioned before, what did it taste like? And we did an experiment, I believe it was about point 1 percent, with phenol. I believe it did kill the bugs but there was an antiseptic taste of phenol showing through the Zantac Syrup. In that example the question I posed was how low can we take phenol and still kill the bugs, plus is phenol acceptable when given by mouth? There is no precedent for it. We took that no further because by that time we had solved the issue with ethanol.

We had something like ten different options bubbling away and ethanol won the race and that describes how

we arrived at ether alcohol. To give us comfort in that could we use ethanol in a syrup for the treatment of ulcers, we were well aware of in the public domain that alcohol was a constituent of Tagamet liquid, so we knew, we knew that another manufacturer was including ethanol. We had no idea why, I still don't know why, but there was a precedent. In fact, the concentration in the SmithKline product was 3 percent alcohol, and I used that concentration as a starting point for my studies.

So I started looking at 3 percent and then I went just under that, 1 percent, just over that, 5 percent. Tested those three against the microorganism and find that 5 did the job and 3 and 1 did not. Then starting with the 5, which is successful, and eventually pitched on the 7.5 to allow a safety margin. That's how we arrived at 7.5 ethanol.

Q Is that work, testing those different ranges of ethanol, is that outlined on the following page of plaintiffs' trial exhibit 242?

A Yes, on that following page it covers all the points that I have just discussed. There are some additional points that I listed here that I have not covered previously. For example I'm looking at phenol ethanol. It's without precedent for oral use but the manufacturers say this is because of the taste. So that is an area where we are really getting into a new area. It's not been done before, which is

were often experiments going on on more than one site and more than one person working on a project at one time, there are frequently more than one book in use at any one time.

Q Dr. Long, is this the project notebook for the Zantac Syrup for this time period?

A It is, yes.

Q Could I direct your attention to page 84337 of trial exhibit 242?

A Yes.

Q Could you please tell the Court what the work is that is reported on this page?

A Yes. The introduction describes the background. It has already been demonstrated that 5 percent ethanol in Zantac Syrup, in brackets it says a preliminary formulation containing methylparaben inhibits the proliferation of the organism. Then it goes on to say that the formulation without methylparaben must also be tested in this way and this page is a description of that experiment.

So what was done was the formulation was made up with, containing ethanol at three different concentrations, 5, 3 and 1 percent.

In addition to that, the other preservatives, propylparaben and butylparaben, were present at 70 percent of their target concentration. Now, this was standard good practice because 70 percent is the lower limit for those

preservatives and would represent the worst case scenario that they could be at during the shelf-life of those products.

So we are testing product, as it were, simulated at the end of its shelf-life in a worst case scenario. In the fullness of time they never actually get down to 70 percent, but that was the lowest we could possibly accept. So we were being thorough in our testing.

Then the results are here for 5, 3 and 1 percent ethanol. I won't go through the actual figures but the conclusion is that the formulation with 5 percent ethanol, it says here that formulation is effective against *Pseudomonas cepacia*. That was a breakthrough. We thought we were back in business, we've killed the bugs.

The next level down, 3 percent, ineffective against the organism, not proceeded any further, backed up. Similar pattern, the 1 percent, conclusion, ineffective against *Pseudomonas cepacia*, not proceeded any further.

So with that result we knew we were back in business providing everything else fell into place.

Q Dr. Long, could I now direct your attention to plaintiffs' trial exhibit 241, please? Could you please relate for the Court the conclusions that you reached in this document?

A Yes, this is another note to my colleague in Zebulon,